

## **EXHIBIT A**

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# Cipla

Therapeutic Index

### Gynaecological Products

#### Forcan TZ KIT

Fluconazole and Tinidazole

#### Composition

Each kit contains  
(A) One Fluconazole Tablet  
Each tablet contains ....  
Fluconazole 150 mg  
Colour: Ponceau 4R  
(B) Two Tinidazole Tablets IP  
Each film-coated tablet contains ....  
Tinidazole IP 1000 mg  
Colours: Titanium Dioxide IP and  
Lake Indigo Carmine

#### Description

Fluconazole is a bis-triazole antifungal structurally related to imidazole-derivative antifungals. The nitrogen of the azole ring of the triazole binds to the haem moiety of the fungus 450 enzyme lanosterol 14  $\alpha$ -demethylase which halts conversion of lanosterol to ergosterol that leads to a cascade of abnormalities in membrane permeability. Fluconazole is active against many fungi including yeasts and dermatophytes. *In vitro*, fluconazole is active against strains of *Candida*, including strains of *C. albicans* and *Torulopsis glabrata*. Tinidazole is a nitroimidazole which has antimicrobial action against *microaerophilic* protozoa, *Giardia lamblia*, *Trichomonas vaginalis* and against obligate anaerobic bacteria. It inhibits DNA strands or inhibition of their synthesis.

#### Indications

**Forcan-TZ** is indicated in the management of vaginal candidiasis, vaginal trichomoniasis, bacterial vaginosis. The kit should preferably be given to both the partners to minimise recurrences.

#### Dosage and Administration

One tablet of fluconazole and 2 tablets of tinidazole as a single oral dose. Both the partners should be treated with this dose to minimise recurrences.

#### Contraindications

Hypersensitivity to either azole group or nitroimidazole group of compounds and in those patients with a history of blood dyscrasias. **Forcan-TZ** kit is also contraindicated in patients with lactation.

#### Warnings & Precautions

##### Drug Interactions

Anticoagulants: Fluconazole has been shown to prolong prothrombin time when given concomitantly with coumarin drugs, hence requires careful monitoring.  
Cyclosporine: Concomitant administration of fluconazole and cyclosporine may result in increase in cyclosporine level.  
Phenytoin: Fluconazole significantly increases phenytoin levels and AUC resulting in phenytoin toxicity.

Oral hypoglycaemics: Concomitant administration of fluconazole and oral hypoglycaemics such as sulphonylurea in diabetic patients results in increased plasma concentration and metabolism of antidiabetic agents.

#### Pregnancy

It is contraindicated in first trimester of pregnancy. There are no adequate and well-controlled studies in pregnant women.

#### Lactation

Since the drug is secreted in breast milk, it should not be used in lactating women.

#### Renal Impairment

Caution has to be taken.

#### Hepatic Impairment

Patients who develop abnormal liver function should be monitored.

#### Side Effects

Fluconazole generally is well tolerated. Nausea, headache, skin rash, abdominal pain, vomiting and diarrhoea are the only commonly reported side effects. The usual symptoms of tinidazole are a metallic taste and mild nausea.

#### Presentation

Each kit of **Forcan-TZ** contains  
One tablet of Fluconazole (150 mg) and  
Two tablets of Tinidazole (1000 mg)

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